DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENU
SAN JUAN, P.R. 00901-3223

HFI-30

M875N

May 1, 1997

WARNING LETTER
SJN-97-12

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Patrick Murphy
President
AGA Gas, Inc.
P.O. Box 94737
Independence, OH 44131

Dear Mr. Murphy:

During an inspection of your compressed medical gas manufacturing facility, AGA Puerto Rico Corp., Road 869, km. 1.8, Barrio Palmas, Cataño, PR, conducted from April 4 to April 14, 1997, our investigators documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's manufacture of Oxygen, USP causing this drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to properly calibrate the oxygen analyzers used for the assay of Oxygen, USP as required by 21 CFR 211.160 (b)(4) in that:

a - The oxygen analyzers were not calibrated in conformance with SOP # QC-03, Calibration and Maintenance Program for Analyzers. The [redacted] and [redacted] had stickers showing the last calibration date to be 12/26/96. The only other oxygen analyzer in the firm, a [redacted] had a sticker showing the last calibration date to be 1/29/97 and was placed "out of service" due to malfunction on 3/11/97. When the units were calibrated on 4/11/97, they were found to be out of calibration. The SOP requires that the [redacted] and [redacted] units be calibrated every two months and that the [redacted] unit be calibrated every three months.

b - The "zero" reading for the [redacted] was not checked once a week with nitrogen gas as specified in the manufacturer's instruction manual for the unit.

2. Failure to have laboratory determination of satisfactory conformance to final specifications for Oxygen, USP prior to release in accordance with 21 CFR 211.165 (a) in that:

a - The Oxygen, USP analysis reports are not reviewed by the supervisor until one or two weeks after the product has been released and distributed. This also is not in accordance with the firm's SOP # QC-12, Analysis Report.

b - Records which showed that the test results were reviewed by the supervisor on the same day as they were performed, before lots of Oxygen, USP were released, were actually reviewed one to two weeks after release and distribution of the products.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility, to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify the San Juan District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions without further notice. These include seizure and/or injunction.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00906-5719, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

Samuel Jones
District Director